EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.g.3(2024)4213783

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
22 - 23 April 2024

CIRCABC Link: *https://circabc.europa.eu/ui/group/95a86e0e-0cfe-4354-8d9f-c447c6e85c1b/library/09141bfb-f622-4f6b-9fb9-57d378c69401?p=1*

SUMMARY REPORT

A.01 Art. 12 and Art. 10 of Regulation (EC) No 396/2005 procedures:

1. Confirmatory data Art. 12 follow-up

a) Cases where EFSA RO has been published

The Commission provided an update on the recently adopted Reasoned Opinions (ROs[1]) on the Article 12 confirmatory data assessment for (i) quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop; (ii) myclobutanil; and (iii) aluminium phosphide and magnesium phosphide.

As regards quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop the European Food Safety Authority (EFSA) assessed an Article 6 application for several products along with the Article 12 confirmatory data. The Commission proposed lowering to or maintaining at the limit of quantification (LOQ) all the maximum residue levels (MRLs) for plant commodities for which data gaps had not been fulfilled. For other plant commodities it proposed setting the MRLs at the levels derived by EFSA. For products of animal origin, the Commission proposed maintaining the current levels. Concerning myclobutanil, EFSA assessed an Article 6 application for several products along with the Article 12 confirmatory data. In view of EFSA's assessment on whether or not the data gaps were addressed by the confirmatory data, the Commission proposed certain MRLs for different products of plant and animal origin.

One Member State enquired about the classification of myclobutanil as possible endocrine disruptor (ED). The Evaluating Member State (EMS) will reply in due course.

Concerning aluminium phosphide and magnesium phosphide, the Commission recalled that its proposal was already agreed at the Standing Committee on Plants, Animals, Food and Feed meeting of 1/2 February 2024.

Member States were invited to submit comments by 13 May 2024.

[1] (i) quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop (doi:10.2903/j.efsa.2024.8560) ; (ii) myclobutanil (doi:10.2903/j.efsa.2024.8746) ; and (iii) aluminium phosphide and magnesium phosphide (doi: 10.2903/j.efsa.2024.8446).

2. Non-approved substances for follow up

a) Update

The Commission informed the Committee that EFSA had launched a Call for expression of interest to submit data for 10 non-approved active substances to review MRLs[2]. The deadline is 7 May 2024 for expression of interest and 8 July for submission of data.

b) Next mandate to EFSA

The Commission reminded of the substances that were agreed for the next mandate to EFSA for a targeted review of the MRLs for non-approved substances.: carbaryl, dicloran, methoprene, phorates, phoxim, pyrasulfotole, quinclorac, saflufenacil, and terbufos. As phoxim is also used in veterinary medical products (VMP), the Commission proposed not to include it in the next mandate as there was a need to first discuss internally within DG SANTE in view of a possible involvement of the European Medicines Agency (EMA).

A.02 Feedback from the section PPP Legislation of this Committee:

1. General issues

The Commission provided an overview of the main outcome of the meetings of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Legislation held in January and March 2024. It gave an update on the table of active substances for which the approval had not been renewed, for which grace periods had expired or will expire soon, and for which follow-up action was therefore needed.

The Commission informed the Committee that dimethomorph had not been renewed as the substance meets two of the cut-off criteria of Regulation (EC) No 1107/2009 (it is toxic to reproduction, category 1B and meets the ED criteria for humans and wild mammals as non-target organisms). In addition, the consumer risk assessment could not be finalised due to several data gaps. A Member State expressed concerns on the impact non-renewal might have on the hops, beer and wine industry if the MRLs were going to be lowered to the Limit of Determination (LOD) without granting transitional measures, as had been decided in case of bifenazate. This was supported by several other Member States. The Commission informed that letters received from stakeholders expressed the same concerns. The draft Regulation on the non-renewal was voted on 21 March 2024 and Member States have 6 months from the date of entry into force to withdraw their authorisations[3]. The Commission reminded that this deadline may not be exceeded. In addition, Member States may grant a grace period of maximum 12 months from the date of entry into force of the Regulation.

The Commission informed the Committee that it plans to mandate EFSA to confirm that the current Toxicological Reference Values (TRVs) cover the ED properties. EFSA will also be requested to review MRLs based on Codex Maximum Residue Limits (CXLs) and import tolerance (IT) and perform the dietary risk assessment by using the

[2] Call for expressions of interest to submit data for 10 non-approved active substances to review MRLs | EFSA (europa.eu)

[3] Commission Implementing Regulation (EU) 2023/918 of 4 May 2023 (OJ L 119, p.160) entered into force on 20 May 2024, therefore authorisations have to be withdrawn by 20 November 2024 and grace periods end on 20 May 2025.

latest version of the Pesticide Residue Intake Model (PRIMo). Whether or not a transitional period for products placed on the market before the application date can be granted depends on the outcome of the EFSA risk assessment.

The Commission invited Member States to inform their stakeholders on possible upcoming changes of MRLs.

2. Endorsement of TRVs for cypermethrin and carbendazim

Cypermethrin: New and lower TRVs for zeta-cypermethrin were derived in the EFSA Article 12 review of the existing MRLs for cypermethrins[4]. The ScoPAFF Section Phytopharmaceuticals - Legislation endorsed the recommended values on 21 March 2024. Carbendazim: Maintaining the existing TRVs was proposed. The same meeting did not endorse the proposed value as there were concerns raised by two Member States with the existing values. In the meantime, EFSA assessed the uncertainties related to the existing TRVs in their recently adopted statement on carbendazim[5]. The endorsement of carbendazim TRVs is now foreseen at the ScoPAFF meeting Section Phytopharmaceuticals -Legislation on 22/23 May 2024.

A.03 Specific substances:

1. Difenoconazole

The Commission updated the Committee on the outcome of the EFSA expert meeting on confirmatory data on preferential degradation of stereoisomers submitted under Regulation (EC) No 1107/2009 held in March 2024. An uncertainty factor of 1.3 for plants and of 2 for animal products are initially proposed. Once the factors are confirmed in the final EFSA RO, the chronic exposure assessment for difenoconazole for wheat and rye will be completed. There may be also exceedances of the acute reference dose for some commodities. The MRLs for wheat and rye are already addressed in the draft Regulation presented under agenda item B.01 of this meeting, a further measure to follow up on the forthcoming EFSA RO will be prepared.

Member States were invited to send comments by 13 May 2024.

2. Sodium silver thiosulfate

In earlier discussions several Member States agreed with the Commission's proposal to include this substance into Annex V of Regulation (EC) No 396/2005. The Commission had consulted the EU Reference Laboratories (EURLs) regarding the residue definition. The EURL's view is that thiosulfate is chemically very unstable and cannot be easily quantified, therefore quantification should rely on silver. Silver is, however, ubiquitous in the environment and the default MRL of 0.01 mg/kg may not cover for natural background levels. The Commission will contact the EURL for heavy metals for additional information on background levels for silver, and then propose MRLs based on the received information.

Member States were invited to submit comments by 13 May 2024.

3. Straight Chain Lepidopteran Pheromones (SCLPs)

---

[4] EFSA, 2023. Reasoned opinion on the review of the existing maximum residue levels for cypermethrins according to Article 12 of Regulation (EC) No 396/2005.EFSA Journal 2023;21(3):7800, 210 pp. https://doi.org/10.2903/j.efsa.2023.7800

[5] EFSA 2024. EFSA Journal. 2024;22:e8569. Updated reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl https://doi.org/10.2903/j.efsa.2024.8569

Straight Chain Lepidopteran Pheromones (SCLPs) are divided into 3 groups, aldehydes, alcohols, and acetates. The Commission gave an update on the inclusion of all SCLPs into Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EU) 2023/1719. The inclusion was based on the assumption that the low-risk status would apply to all SCLPs while only acetates are approved as low risk substances. At the previous meeting of this Committee, several Member States supported maintaining all SCLPs in Annex IV, mostly because negligible consumer exposure is expected due to their high volatility and rapid dissipation in air, when used in line with the approved GAPs. Other Member States expressed concerns as EFSA noted in its Conclusion[6] the presence of residues of one SCLP alcohol in one of the residue trials. Residues found in that specific case are most likely due to an application not in accordance with the GAP (i.e., spray application in late autumn, when the low temperatures might have led to the solidification of the substance). One Member State noted that spray applications are often made in third countries and that GAPs approved there may be similar to the trial mentioned above leading to residues. The Commission informed the Member States of a stakeholder's letter clarifying that the consumer exposure from the use of spray applications of SCLPs is low due to the intrinsic characteristics (e.g., high volatility and rapid dissipation in air). A total of 19 residue trials have been conducted on different crops with different SCLPs (alcohols and acetates) in the EU. The residue on the treated commodity was below the Limit of Quantification (LOQ) from the same day of the last application in both residue zones and in all the trials (except the above mentioned one). The Commission clarified that SCLPs are mostly applied by dispensers, and that they are manufactured cross the globe, and therefore all GAPs are very similar. The use of SCLP in late autumn, as it was made in the trial where residues were found, is extremely unlikely also in third countries. Due to the low temperatures, the target pest is absent in those periods and the overapplication of pheromones is counterproductive. Therefore, the Commission proposed to maintain all SCLPs in Annex IV of Regulation (EC) No 396/2005.

Member States were invited to submit comments by 13 May 2024.

4. Imazalil

The ongoing evaluation of Article 12 confirmatory data for imazalil was already discussed at the last meetings of this Committee in November 2023 and February 2024. The Evaluating Member State (EMS) informed the meeting that the applicant had shared the outcome of the repeated in vitro micronucleus study with metabolite FK772 to address the data gap on genotoxicity. The study clearly shows a non-genotoxic potential of this metabolite. The EMS will finalise the assessment of the study soon and will submit the outcome to EFSA. The Commission invited the EMS to provide an update on the ongoing renewal process of imazalil under Regulation (EC) No 1107/2009.

5. *Bacillus thuringiensis* (Bt)

The Commission updated the Committee on the latest developments. The Commission is internally discussing the possibility to mandate EFSA to provide a scientific opinion on the possible enterotoxigenic potential of Bacillus thuringiensis strains approved for plant protection purposes in order to support a risk assessment.

[6] EFSA 2021. Conclusion on the peer review of the pesticide risk assessment of the active substance Straight Chain Lepidopteran Pheromones (SCLPs). EFSA Journal2021;19(6):6656, 30 pp. https://doi.org/10.2903/j.efsa.2021.6656

6. Bifenazate

The Commission noted that the Regulation[7] lowering all MRLs of bifenazate to the LOD was published on 22 March 2024 and it will become applicable on 14 October 2024.

7. Etoxazole

The Commission informed the Committee that the correcting Regulation of the Spanish, Czech, German and Italian language versions of Commission Regulation (EU) 2023/1783 is currently under scrutiny by the European Parliament and the Council with a deadline of 14 May 2024. The adoption of the correcting Regulation is foreseen in June 2024. The issue was discussed more in depth in the Committee on 1/2 February 2024 (agenda item A. 15.06)

8. Glufosinate

The Commission informed the Committee that the mandate to EFSA according to Article 43 of Regulation (EC) No 396/2005 is under preparation. Stakeholder interest, including applicants and Third countries, in this substance is very high.

9. Matrine

Following the discussions held at the last meeting of this Committee in February 2024, one Member State requested the Commission to send a mandate to EFSA, under Article 43 of Regulation (EC) No 396/2005, to perform a harmonised risk assessment for matrine and endorse the Opinion No. 67/2023[8] of the German BfR on liquorice. The Commission confirmed that the requested EFSA assessment could be useful, but noted that the time horizon for this request would depend on EFSA's workload on other priorities. In the meantime, Member States were invited to use the German Opinion to guide their enforcement actions on liquorice.

Two trade associations - Chocolate, Biscuits and Confectionery of Europe (CAOBISCO) and Tea and herbal Infusions Europe (THIE) - sent a joint letter to the Commission informing that import tolerance applications were not possible. They claim that liquorice roots themselves do not contain matrine/oxymatrine, but that they are present in the crop due to an unintentional and unavoidable co-harvest of *Sophora flavescens*. The setting of a temporary MRL (tMRL) would be an option in their view. However, it is not clear on what basis such a tMRL would be set. One Member State confirmed that a very low level of co-harvest can lead to MRL exceedances. A Member State suggested to carry out a toxicological assessment as a first step.

Member States were invited to send comments by 13 May 2024.

10. Ethiprole

The Commission noted that the applicant had changed the purpose of the application from "set import tolerance" to "amend existing residue definition" which would include a toxicological assessment of ethiprole and its metabolites to conclude on toxicological endpoints This was necessary as the applicant had not submitted the required data to address the data gap on residue trials and therefore the import tolerance request could

[7] Commission Regulation (EU) 2024/891 of 22 March 2024 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate in or on certain products OJ L, 2024/891, 25.3.2024.

[8] The German Federal Institute for Risk Assessment (BfR) examines the health risk of residues plant-alkaloids-in-liquorice-roots-genetic-damage-by-matrine-and-oxymatrine-unlikely.pdf (bund.de)

not progress. EFSA is therefore drafting a RO limited to the assessment of the toxicological properties of ethiprole.

One Member State suggested to modify the import tolerance application form in order to systematically allow for toxicological data assessment in order to support the process of evaluation of possible future Codex maximum residue limits (CXLs). The Commission considered setting a parallel process to the already existing process on evaluating CXLs not advisable but will further reflect on the suggestion.

Member States were invited to send comments by 13 May 2024.

11. Nicotine

The Commission proposed to set an MRL of 0.05 mg/kg for nicotine in coffee beans. This proposal follows a call for monitoring data to EFSA and to the European Coffee Federation (ECF) and includes advice received from the EURLs. No comments were received during the meeting. Member States were invited to send comments by 13 May 2024.

12. Dimethomorph

(See agenda item A 02.01).

A.04 News from and files related to the European Food Safety Authority:

1. Progress under Articles 6 and 10 of Regulation (EC) No 396/2005

EFSA reported that outputs addressing 3 processes had been adopted since the previous meeting of this Committee.

Currently, outputs addressing 29 processes are at different stages of the procedure. Out of these, 7 are under scientific assessment (4 under Regulation (EC) No 396/2005 and 3 under Regulation (EC) No 1107/2009) and 22 under clock-stop, as additional data had been requested (16[9] under Regulation (EC) No 396/2005 and 6 under Regulation (EC) No 1107/2009).

2. Progress under Article 12 of Regulation (EC) No 396/2005

Since the previous meeting of this Committee, EFSA finalised reviewing 1 active substance, data are pending in the case of 5 active substances, the review of 19 active substances is on hold and the assessment of 6 active substances is ongoing.

The progress report table is publicly available for interested stakeholders[10].

3. Update on other mandates (Articles 29 and 31 of Regulation (EC) No 178/2002, and Article 43 of Regulation (EC) No 396/2005

EFSA finalised 1 assessment under Article 31 of Regulation (EC) No 178/2002 and 4 assessments under Article 43 of Regulation (EC) No 396/2005.

In total, 11 scientific assessments are ongoing relating to active substances, the Codex Committee on Pesticide Residues (CCPR) mandate 2024, fall-back MRLs for revoked CXLs and to the International Estimate Short-Term Intake (IESTI) methodology.

[9] Each process receives a so called "EFSA question number".
[10] https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf

4. Other issues:

Mandate on Cumulative Risk Assessment (CRA)

Public consultation is ongoing on a draft scientific report on specific effects on liver relevant for performing dietary retrospective CRA of pesticide residues. The deadline is 23 May 2024.

Regarding prospective CRA, the acute mock assessment (tefluthrin/carrots) and the chronic mock assessment (fenamidone/lettuce) reports are under finalisation.

EFSA and the National Institute for Public Health and the Environment (RIVM), Netherlands are organising a training on the open access Monte Carlo Risk Assessment (MCRA) tool for prospective CRA. Competent authorities of the Member States are the target audience. For beginners, the training dates are 2 May and 10 June 2024. Invitations have been sent to members of the Pesticide Steering Network.

PRIMo 4

EFSA shared the main improvements of PRIMo 4, a comparison of results derived with PRIMo 3.1 and Primo 4 (beta version), and the next steps. The planned publication date of PRIMo 4 is June 2024.

PSN/Transparency/IUCLID

EFSA informed the Committee that the next IUCLID PSN meetings will be held on 11-12 June (hybrid) and in November (date to be confirmed, online).

A virtual tour of Member States is ongoing, and Member States interested in such bilateral meeting are invited to contact EFSA at pesticide.mrl@efsa.europa.eu.

EFSA Guidance on the assessment of pesticide residues in rotational crops[11]

Training by EFSA on the Guidance is planned for second semester and details will be provided in due course.

EFSA Annual Report on Pesticides Residues in Food

EFSA provided an overview of its annual monitoring report[12]. A data visualisation tool[13] of both the EU multi-annual control programme (EU MACP) and the National Control Programmes (MANCP)(s) is also available. In the reporting year of 2022, 96.3% of the overall 110,829 samples analysed were below MRL, 3.7% exceeded this level, of which 2.2% were non-compliant. For the EU MACP subset, 11,727 samples were analysed of which 0.9% were non-compliant.

In their report EFSA made a number of recommendations to the reporting Member States.

EFSA Administrative Guidance on pesticides

EFSA provided an update on the ongoing revision of the Administrative guidance on submission of dossiers and assessment reports for the peer review of pesticides active substances and on the MRL application procedure. Endorsement by both sections of the Committee (Phytopharmaceuticals- Legislation and Residues) will take place at the meeting of the section Phytopharmaceuticals – Legislation on 22-23 May 2024. EFSA

[11] EFSA 2023. Guidance on the assessment of pesticide residues in rotational crops. EFSA Journal, 21(11), 1–86. https://doi.org/10.2903/j.efsa.2023.8225.
[12] https://www.efsa.europa.eu/en/efsajournal/pub/8753
[13] https://multimedia.efsa.europa.eu/pesticides-report-2022

announced it would circulate the document for comments to Member States after this meeting.

A.05 Alignment of certain MRLs for pesticides and veterinary medicinal products:

The Commission presented an overview table on the ongoing work on the alignment of MRLs for multiple use substances. In particular, the Commission noted that phoxim (which has MRLs set both as pesticides and VMP) will not be included in the second mandate for an EFSA targeted review of the MRLs for non-approved substances pending a decision about how to address this dual use substance (see agenda item A 01.02.b).

For substances used both as pesticides and as biocides, the Commission presented an update on recent activities on chlorocresol (4-chloro-3-methylphenol) and lambda-cyhalothrin. The Commission requested EFSA to provide recent monitoring data for both substances to assess if levels higher than the default MRL of 0,01 mg/kg were found in food, as those findings may have originated from a biocidal use and may therefore justify setting tMRLs. No recent monitoring data for chlorocresol were available. For lambda-cyhalothrin, recent monitoring data show exceedances of the default MRL in commodities from poultry and bird's eggs. Therefore, the Commission mandated EFSA to assess potential health risks to EU consumers if tMRLs were derived from available monitoring data (i.e., 0.03 mg/kg in commodities from poultry and 0.02 mg/kg in bird's eggs). Based on the outcome of the EFSA's assessment, the Commission may consider proposing modifying the MRLs for lambda-cyhalothrin in those products.

Member States were invited to submit comments by 13 May 2024.

A.06 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that expire in 2023-2024:

1. General overview

The Commission provided an update on the state of play for chlormequat in cultivated fungi, nicotine in coffee beans, chlorpropham in potatoes, mepiquat in cultivated fungi, and 1,4-dimethylnapthalene in food commodities (except potatoes). The Commission encouraged Member States to approach their national mushrooms growers' associations to request monitoring data, particularly on oyster mushrooms.

Member States were invited to submit comments by 13 May 2024.

A.07 International Matters:

1. OECD Guidance document on the definition for risk assessment

The latest version of the draft guidance document will be shared with the OECD Residue Chemistry Expert Group for their review followed by a public consultation and a review by the OECD Working Party of National Coordinators of Test Guidelines Programme and the OECD Working Party on Pesticides.

2. OECD Honey Guidelines

The OECD working group continues to review the large number of comments received during the pre-commenting period and aims to finalise the comments by summer 2024.

3. OECD Guidance on Stability of Pesticide Residues in Stored Commodities

The OECD working group is in the process of finalising the draft guidance document. The aim is to have the draft ready by end of April and send it to the OECD Residue Chemistry Expert Group for their review. A second commenting period is envisaged for the third quarter of 2024 involving members of the OECD Working Party on Pesticides. The aim is to finalise the work by the end of 2024.

4. OECD Guidance Document on Pesticide Residue Analytical Methods

No information was reported, an update will be provided once the draft has been finalised.

5. Codex Alimentarius/JMPR issues

1. Update on EFSA mandates

The Commission prepared a draft mandate to follow-up on EU reservations made at CCPR in the past based on evaluations ongoing in the EU. The Commission is now negotiating it with EFSA. A second mandate for EFSA to assess whether action is needed on CXLs revoked by the Codex Alimentarius Commission (CAC) in the past is foreseen but was put on hold.

2. Substances for CCPR 55

The Commission referred to an email sent on 12 April 2024 on the common EU positions based on the risk assessment included in the draft EFSA report available on the EFSA Document Management System. The Commission asked Member States to signal issues on which they may not agree with the EFSA conclusions on the assessment of the JMPR report and which would need to be discussed with priority in the first Council Working Party in view of finding a harmonised EU position.[14]

Member States were invited to submit comments by 29 April 2024.

A.08 Cumulative Risk Assessment (CRA):

The Commission reminded the Committee of the upcoming webinar organised by the Management Board of Partnership for the Assessment of Risk from Chemicals (PARC) on integrative risk assessment and real-life mixtures using human biomonitoring data. Deadline for registration was 17 April 2024.

The Agence Nationale Sécurité Sanitaire Alimentaire Travail (ANSES, France) provided an update on the progress of the mock assessments for CRA and indicated that both the acute and the chronic prospective assessments will be completed shortly.

A.09 Sampling Regulation – Feedback from WG and next steps:

The second and last meeting of the Sampling Working Group took place on 19 March 2024. The minutes of that meeting and a draft proposal for a new Sampling Regulation replacing Commission Directive 2002/63/EC was shared with Member States. The final discussions of the draft measure will continue at this Committee.

[14] Report 2023: pesticide residues in food: Joint FAO/WHO Meeting on Pesticide Residues. https://www.who.int/groups/joint-fao-who-meeting-on-pesticide-residues-(jmpr)

A.10 Notifications under Article 18(4) to Regulation (EC) No 396/2005:

No matters were raised under this agenda item.

A.11 Designation of Member States for maximum residue levels (MRL) applications:

A Member State informed the Commission that they had received an import tolerance application for diquat, a non-approved substance in the EU, and would like to proceed with the evaluation. The co-Rapporteur Member State (RMS) agreed to carry out the evaluation.

(Note: following the most pragmatic approach agreed earlier, the previous RMS or co-RMS of the same substance should do the evaluation if the approval of the substance was not renewed).

A.12 Forthcoming draft Regulations (indicative only):

1. Gamma-cyhalothrin Article 12

The Commission updated the Committee on the forthcoming draft Regulation reviewing the MRLs for gamma-cyhalothrin under Article 12 of Regulation (EC) No 396/2005.

A.13 Issues related to Annex IV to Regulation (EC) No 396/2005:

The Commission informed the Committee that it had incorporated the list of non-approved basic substances for which the default MRL of 0.01 mg/kg applies into the Excel table of non-approved substances considered to be food.

At the previous Committee meeting, it was decided to keep applying, in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005, the default MRL of 0.01 mg/kg for non-approved basic substances. At this meeting, the Commission proposed to add one of these substances, potassium sorbate, to Annex IV of the same Regulation with the footnote "Substances included in Annex IV without prejudice to other specific food and/or feed legislation, e.g. on food additives, feed additives, food supplements, flavourings, etc".

The Commission sought advice from Member States on non-approved substances which are considered food according to Regulation (EC) No 178/2002[15]. For them currently the default MRL of 0.01 mg/kg applies according to Article 18(1)(b) of Regulation (EC) No 396/2005, which can neither be enforced, nor does it seem appropriate. Annex IV inclusion would be an option, however, there is no additional information available (e.g. review reports or applications) to support this.

Furthermore, some of the substances e.g., coconut oil, maize oil, soya oil that could in principle be added to Annex IV of Regulation (EC) No 396/2005 are however classified as substances or products causing allergies, intolerances under Regulation (EU) No 1169/2011[16] and labelling is required. EFSA has identified some substances which are

[15] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

[16] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament

listed also in the EFSA Compendium of Botanicals[17] that contain naturally occurring substances of possible concern for human health when used in food and food supplements.

One Member State suggested dividing Annex IV of Regulation (EC) No 396/2005 into two parts. One part could include substances which are not possible to enforce because of some missing elements, e.g., residue definition, methods of analyses etc. The second part would include substances where all those elements are available. Active substances that are food, could be included in the first part. The Commission proposed further discussion this matter.

Member States were invited to send comments by 13 May 2024.

A.14 Issues related to Annex I to Regulation (EC) No 396/2005:

The Member State leading the working group on the footnote 1 of Annex 1 to Regulation (EC) No 396/2005 provided an update on the progress made with a guidance document on the interpretation of the footnote. Some examples were shared, where Member States participating in the working group, were of diverging views. The Commission requested all Member States to provide their interpretation on those specific cases.

The Commission reported about a meeting it had with a stakeholder associations the EU vegetable oil and protein meal industry association (FEDIOL), European Feed Manufacturers' Federation (FEFAC) and the European Association of cereals, rice, feedstuffs, oilseeds, olive oils and fats agrosupply trade (COCERAL) touching also on this subject. A stakeholder consultation is planned at a later stage.

Member States were invited to submit comments by 13 May 2024.

A.15 New proposals for Table 3 of the extrapolation guidelines (SANTE/2019/12752 Rev01).

The Commission summarised the proposals received from Member States considering new extrapolations to be included in an updated version of the table 3 of Appendix D of the Extrapolation Guidelines[18]. EFSA and one Member State stressed the importance to harmonise this table with the recommended extrapolations defined by Codex Alimentarius and include those that are in line with the EU extrapolation rules.

Member States were invited to submit comments by 13 May 2024.

A.16 EFSA Guidelines on rotational crops – for endorsement by Member States:

The Commission pointed out that the Guidance on the assessment of pesticide residues in rotational crops[19] supports the practical implementation of the relevant OECD Test Guidelines. It illustrates individual steps of the assessment with flow charts, practical examples, and technical advice on how the provisions of the OECD Documents should

---

and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22/11/2011, p. 18)

[17] https://combodb.ecomole.com/report/

[18] Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752, revision 1, 10 May 2023).

[19] EFSA 2023. Guidance on the assessment of pesticide residues in rotational crops. EFSA Journal, 21(11), 1–86. https://doi.org/10.2903/j.efsa.2023.8225

be applied to be in line with the EU regulatory requirements. In general, the EFSA guidance document provides clarifications on points for which the data requirements of the existing guidance documents were not interpreted in a consistent manner or left room for divergent interpretations.

The proposed date of implementation is 1 January 2025 for all dossiers including those of which the evaluation is ongoing. A case-by case pragmatic judgement is needed on how to deal with ongoing assessments.

EFSA clarified, in response to comments from Member States, that the Guidance is a living document and is not mandatory. Its aim is to help assessing submitted information (e.g. soil analysis) and not to set additional requirements. In the case of import tolerance applications, the assessment of residues resulting from uptake via soil related to previous uses of the active substance in the preceding crop is not specified in the Guidance. In addition, EFSA confirmed that the level of conservatism implemented at MRL setting should be discussed by risk managers.

The Commission will inform the section Phytopharmaceuticals-Legislation of this Committee in May 2024. Further discussions on any outstanding issues of the Guidance and the endorsement are foreseen at the next meeting of this section of the Committee on 23/24 September 2024.

Member States were invited to send comments by 13 May 2024.

A.17 Other Information points:

1. Article 19 of Regulation (EC) No 396/2005 translations

The translation error of the wording of the Dutch and French version of Article 19 of Regulation (EC) No 396/2005 will be rectified in the coming weeks. Its publication is expected by mid-May 2024.

2. Chlorate- question from a Member State

A Member State reported that exceedances of the current tMRLs set for chlorate had been detected in certain vegetables particularly brassicas. The origin of chlorate is assumed from fertiliser or as disinfectant uses and not from unauthorised uses of PPPs. Adaptation of those MRLs were suggested in the light of such new data. The Commission reminded the Committee that the chlorate MRL Regulation[20] is only one element of the chlorate action plan adopted in 2017[21] to reduce chlorate levels resulting from uses other than fertiliser and that the review of chlorate MRLs would remain scheduled for 2025 as foreseen in the recitals of that Regulation. A new EFSA data collection and risk assessment may be necessary.

3. Piperonylbutoxide – question from a Member State

Piperonylbutoxide is a biocide and a synergist in plant protection products, therefore no EU MRLs are set under Regulation (EC) No 396/2005. A Member State raised a question on whether other Member States have set national MRLs in this case and at what levels. Sharing this information would be useful to facilitate trade in the single market.

[20] Commission Regulation (EU) 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products, OJ L 178, 8.6.2020, p. 7.
[21] https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/chlorate_en

Member States were invited to send information on their national MRLs for piperonylbutoxide by 13 May 2024.

4. Presence of chlormequat in sunflower

Following the meeting of this Committee on 1/2 February 2024, one Member State shared written information on their control results of sunflower seed from another Member State. In 2022, 21 samples of sunflower seed were reported as part of official food monitoring, 3 of which contained residues of chlormequat. One of these 3 samples contained chlormequat above the MRL. The 3 samples submitted in 2023 were found to be compliant. The Member State pointed out that chlormequat is not authorised for use in sunflowers and asked for further information about the findings of chlormequat in sunflower seeds and measures taken by the other Member State in question.

5. Member States' submission of the multiannual national control programmes for pesticides residues

The Commission clarified that there is no legal obligation for Member States to submit their multiannual national control plans (MANCPs) for pesticides residues to EFSA or to the Commission. These rules changed when the Regulation (EU) 2017/625[22] (OCR) entered into force. According to Article 111 of the OCR, MANCPs shall be regularly updated and made publicly available. Sending them to EFSA is possible but not mandatory and the information is saved in a dedicated Teams channel.

6. Update on acetamiprid

The Commission gave a short update on the soon-to-be published EFSA Statement on the toxicological properties and MRLs of acetamiprid and its metabolites. Next steps for MRLs, including the relevant part of SANTE/11278/2021 will be discussed at the next meeting of this Committee on 23/24 September 2024.

Member States were invited to send any preliminary views by 6 May 2024.

7. Approach to copper analysis

A preliminary survey was conducted ahead of the proficiency test for copper. The EURLs concluded that there are discrepancies among Member States in the way samples are taken and treated in official laboratories prior to copper analysis. Some laboratories follow the protocol for contaminants, others the protocol for residues and others do both. The Commission stressed that for purposes of residue monitoring and enforcement, the protocol for pesticide residues should always be used, and the protocol for contaminants would not give valid results as the samples are washed before analysis. EFSA noted that when reporting, until this year, there had been an option to indicate which protocol had been used.

EFSA proposed that this topic could be discussed with data providers for pesticide monitoring results and contaminants from all Member States at the Chemical Monitoring data collection Network meeting to be held on 22/23 October 2024.

Member States were invited to send their comments by 13 May 2024.

8. Forchlorfenuron

One Member Stated called for a mandate under Art 43 of Regulation (EC) No 396/2005 to EFSA to conduct a review of the residue definition for forchlorfenuron in view of

[22] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities; ELI: http://data.europa.eu/eli/reg/2017/625/oj

the recent EFSA Conclusion on the peer review. This recent study suggests that the previous residue definition does not sufficiently reflect the expected residues for the determination of consumer exposure. The Commission sought the views of the Member States, who were invited to send their comments by 13 May 2024.

9. MRLs for herbal infusions

One Member State requested clarifications on the MRLs that should apply to different new types of herbal infusions on the market (such as bitter melons or thyme). The question is whether the MRL should be based on the MRL of the existing commodity in Annex I (with a processing factor, if necessary) or if it should be the MRL for the category 0639000 (d) any other parts of the plant.

Member States were invited to send their comments by 13 May 2024.

10. Technical instructions for French local authorities to implement the National measure on thiacloprid

The Note from the French Authorities was shared on CIRCA BC.

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chitosan, clopyralid, difenoconazole, fat distillation residues, flonicamid, hydrolysed proteins, and lavandulyl senecioate in or on certain products

(PLAN/2024/791)

The Commission presented revision 4 of the draft Regulation, intended to set MRLs for clopyralid, difenoconazole, and flonicamid based on applications for new or modified MRLs and to include chitosan, hydrolysed proteins, fat distillation residues and lavandulyl senecioate in Annex IV.

One Member State enquired about the short-term exposure of difenoconazole in kale. EFSA clarified that the conclusion for kales needs to be revised in order to apply a new uncertainty factor which was recently agreed by the residue experts meeting on difenoconazole in the context of the peer review on confirmatory data (see point A.03.1). EFSA pointed out that the new data will be made available for the Committee to revise the previous conclusion.

One Member Stated questioned the timeline. The Commission explained that some delays can be expected due to the recess period of the European Parliament.

One Member State enquired about flonicamid belonging to the group of PFAS (Per- and polyfluoroalkyl substances), and currently also under discussion under REACH. The Commission explained that internal discussions are ongoing on PFAS more generally and committed to provide an update when available. It was noted that trifluoroacetic acid (TFA) merits special attention as there is not information available coming from the monitoring programmes. The Commission will consider if adding TFA to MANCP and NCP programmes is feasible, also from an analytical point of view.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fosetyl-Al, potassium phosphonates and disodium phosphonates in or on certain products

(PLAN/2023/138)

The Commission presented revision 7 of the draft Regulation. As residues of the parent substance 'fosetyl' may be found in some crops in certain circumstances, if 'fosetyl' was to be deleted from the residue definition for enforcement for the three active substances, the default MRL of 0.01 mg/kg would apply according to Article 18(1)(b) to Regulation (EC) No 396/2005. This would be an unintended consequence. Therefore, the new revision proposes the establishment of 'fosetyl' as a standalone residue, but clarifying that the same MRL as for phosphonic acid would apply to residues of 'fosetyl', hence the default MRL of 0.01 mg/kg would not apply to fosetyl.

One Member State agreeing with the suggested approach proposed some editorial changes for a more harmonised interpretation of the legal text. Another Member State proposed additional editorial changes with the same purpose. A further Member State expressed concerns on the Acceptable Daily Intake (ADI) used by EFSA in its assessment of the MRLs for fosetyl-Al, potassium phosphonates and disodium phosphonates that are the basis for the current draft Regulation. EFSA used the ADI of 1 mg/kg bw/day that was endorsed at the SCoPAFF section Phytopharmaceuticals – Legislation in May 2023. Review of the ADI was considered during the ongoing peer review for approval of choline hydrogen phosphonate, a new phosphonate active substance, considering differences in molecular weight, and applying a lower ADI as potential consumer risks may occur.

The Commission invited EFSA to provide its views on the raised issue, to ensure that the proposed regulation does not pose a risk to consumers. EFSA noted that this issue has been previously discussed, and that it was agreed that such a recalculation of the ADI was not needed. It also noted that the JMPR also got to the same conclusion and is using the same ADI. Lastly, EFSA proposed that this issue could be further investigated in the framework of the evaluation of choline hydrogen phosphonate.

Germany provided the following statement:

"*Overall, Germany can only support this draft regulation as an interim solution. We have doubts about the legal security of the provisions to avoid the applicability of the default value in the case of fosetyl findings, as the combination of an additional column for fosetyl with the chosen text of the footnote does not appear to be legally unambiguous. In our view, the inclusion of fosetyl in the residue definition is still the only unambiguous, consistent and legally secure way forward*."

The Commission recalled that the proposed text had been approved in the Commission's internal consultation procedure and noted that the residue definition for all phosphonates may be reconsidered once the EFSA assessment of choline hydrogen phosphonate is concluded, and MRLs may then be recalculated if appropriate.

The Commission proposed some additional amendments of the legal text to further ensure coherence and clarity and presented revision 8 of the draft measure for vote.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benomyl, carbendazim and thiophanate-methyl in or on certain products

(PLAN/2022/2853)

The Commission presented revision 10 of the draft Regulation. As agreed at the previous meeting on 1/2 February 2024, the Commission mandated EFSA to carry out a follow-up qualitative assessment of the data gaps that were identified for the studies used in the framework of the assessment of the TRVs for carbendazim. The aim of the assessment was to confirm the reliability of the derived TRVs and to explain the way uncertainties were addressed. The Commission revised the draft Regulation to include the outcome of the EFSA assessment, which confirmed that the TRVs are protective for consumers. In addition, the new draft does not propose to increase any of the safe MRLs based on import tolerances any longer but to either maintain them at the existing level or to lower them to a new level proposed by EFSA, where available. Lastly, the new revision proposes to modify the residue definitions for carbendazim and thiophanate-methyl in animal products, as recommended by EFSA in its Article 12 review.[23]

One Member State expressed appreciation for the rapid reply by EFSA on the TRVs for carbendazim, proposed some minor editorial changes to the text to address some clerical errors and informed that it can support the proposed draft Regulation. One Member State announced it could not support maintaining MRLs based on import tolerances for non-approved substances, another one did a case-by-case assessment and cannot support the proposed MRLs due to the substance meeting the cut-off criteria (classified R1B) under Regulation (EC) No 1107/2009.

Another Member State noted that, while it highly welcomed the lowering of the majority of the MRLs to the LOQ, it would nevertheless abstain as some MRLs were maintained on the basis of import tolerances and the substance meets the cut-off criteria. Another Member State expressed their support of the proposal as MRLs are lowered for the vast majority of commodities.

France provided the following statement:

"F*rance reiterates its opposition to the establishment or maintenance of MRLs, including CXLs and import tolerances, for substances that present one or more exclusion criteria for human health, and The proposed draft regulation on maximum residue limits for carbendazim and thiophanate-methyl undermines the objective of establishing fair competition at global level and in the internal market, whereas the European Council of 17-18 April, on the contrary, "encouraged the Council and the Commission to continue their work, particularly with regard to (...) ensuring competition based on fair rules at global level and in the internal market" [point 22 of its conclusions]. In a context where our farmers are very concerned about the risk of unfair competition arising from products imported into the EU from third countries,*

[23] EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for thiophanate-methyl and carbendazim according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(12):3919, 118 pp. https://doi.org/10.2903/j.efsa.2014.3919.

France would like to stress that European regulations are therefore expected to guarantee that the use of substances banned in the EU because of their harmful effects on health, biodiversity or the climate will not be supported and amplified by the import of agricultural products from third countries that authorise these substances. This is why agricultural products treated with such substances should not be allowed access to the internal market and the corresponding MRLs should therefore be lowered to the Limits of Quantification. In this context, France invites the Commission to reconsider its proposal in the light of the dual imperative of equity and environmental coherence, the importance of which we are reminded by the response to the crisis in the agricultural sector."

The Commission addressed the clerical mistakes identified by one Member State and presented revision 11 of the draft measure for vote.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards radish leaves

(PLAN/2023/2900)

The Commission presented revision 2 of the draft Regulation on the classification of radish leaves in Part B of Annex I to Regulation (EC) No 396/2005. The draft Regulation proposes the reclassification of small radish in Part B of Annex I under rucola. Further Regulations will be needed to set MRLs of small radish leaves for chlorantraniliprole, mandipropamid and oxathiapiprolin. This draft Regulation was submitted to the Commission's feedback mechanism where 8 comments had been received, from citizens (2), a company (1), NGOs (2) and food business organizations (3). From the 8 comments, 5 were considered not relevant as they were not related to the topic of this Regulation and 3 supported the draft Regulation without proposing amendments. Therefore, the draft was not modified after the consultations.

The Commission suggested a way forward for the leaves of other crops (such as carrots) that might be consumed but are not explicitly mentioned in Annex I to Regulation (EC) No 396/2005. Following a pragmatic approach applying the MRLs from the category Others of the subgroup (f) herbs and edible flowers (code 0256990) was proposed.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and III to Regulation (EC) No 396/2005 as regards maximum residue levels for cyproconazole and spirodiclofen in or on certain products

(PLAN/2023/1960)

The Commission presented revision 3 of the draft Regulation and gave an overview of its contents and the modifications made since the previous meeting of this Committee. The Committee discussed the comments received from two third countries following the consultation of trading partners under the World Trade Organization Sanitary and Phytosanitary measures (WTO-SPS) agreement. One Member State abstained from the vote as the substances meet the cut-off criteria in Regulation (EC) No 1107/2009. Five Member States did not support the draft Regulation as they had concerns with including MRLs based on import tolerances for substances not approved in the EU and/or meeting

the cut-off criteria (cyproconazole and spinosad being classified as R1B). One Member State abstained due to the risk of unfair competition arising from products imported into the EU from third countries that contain substances not approved in the EU. France requested the same declaration as presented under agenda item B.03 to be included in the Summary Report of this meeting, which was noted by the Committee.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annex II to Regulation (EC) No 396/2005 as regards maximum residue levels napropamide, pyridaben and tebufenpyrad in or on certain products

(PLAN/2023/2190)

The Commission presented revision 3 of the draft Regulation and gave an overview of its contents and the amendments made since the previous meeting of this Committee. The Committee also discussed the comments received from two third countries following the consultation of trading partners under the WTO-SPS agreement.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, famoxadone, flutriafol, mandipropamid and mefentrifluconazole in or on certain products

(PLAN/2024/817)

The Commission presented revision 4 of the draft Regulation intended to implement Codex maximum residue limits (CXLs) into EU legislation for which the EU has not made reservations at the 54th session of the CCPR in 2023.

One Member State indicated they will vote against of the proposal because it considers that the European toxicological assessment for flutriafole is obsolete and that there is no harmonised classification. No further comments were received.

Vote taken: Favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for cypermethrins in or on certain products

(PLAN/2023/1863)

The Commission introduced the comments received from Member States since the previous meeting. A response to the WTO-SPS notification was received from two third countries requesting to maintain the MRLs for some products of animal origin and for tea. However, health risks have been identified with these MRLs so that it is not possible to maintain the levels. A letter was also received from a stakeholder stressing that analytical methods are available for alpha-cypermethrin.

The Commission presented an alternative approach for the draft Regulation. Two sets of MRLs are proposed: one set for cypermethrin (sum of isomers) and one set for alpha-cypermethrin. With this approach, there would be no need to lower the MRLs for

cypermethrin (sum of isomers) to the LOQ for those 34 commodities previously identified by EFSA as presenting a health risk if all residues consisted of the more toxic alpha-cypermethrin, since a separate safe limit would be set with the MRL for alpha-cypermethrin. It would also allow for staying aligned with CXLs as CXLs are set for cypermethrin (sum of isomers). The MRLs for alpha-cypermethrin would be derived by EFSA based on the GAPs for alpha-cypermethrin reported to JMPR to support CXLs, converting the residue trial results to alpha-cypermethrin with appropriate conversion factors. The EURLs confirmed that current validated analytical methods for cypermethrin can be used to measure alpha-cypermethrin. Some Member States raised concerns that laboratories would need validation and accreditation for a new method. The Commission suggested that proficiency tests could be conducted by the EURLs.

Member States were invited to send their comments by 29 April 2024.

C.02 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for dithiocarbamates in or on certain products

(PLAN/2023/2019)

The Commission presented revision 2 of the draft Regulation and the modifications performed compared to the previous version. Following the suggestion received by a Member State, the proposed Residue Definition for enforcement was simplified to "dithiocarbamates (dithiocarbamates determined and expressed as CS_2)", to cover the background levels and removing the list of specific substances in the residue definition. Levels based on previously authorised EU uses of metiram were modified as the substance is no longer approved in the EU and any grace period provided by Member States will expire before the adoption of this draft Regulation. The Commission noted that after clarifications from EFSA, the proposed value for currants will be amended in the next revision based on the group MRL at 2 mg/kg.

The Commission indicated that due the lack of analytical methods to quantify specifically the individual substances or groups of substances, the current draft Regulation is proposing MRLs for carbon disulfide (CS_2), which might be present in food products as a result of the use of different dithiocarbamates or due to natural occurrence. Once analytical methods will be available for the main groups of dithiocarbamates[24] the proposed MRLs for CS_2 will not be necessary any longer and should be deleted. At international level, dithiocarbamates are prioritised to be included under periodic review and the joint FAO/WHO Meeting for Pesticides residues (JMPR) is defining the strategy for their evaluation. The Commission mentioned several letters from food business operators highlighting the importance of mancozeb in the production of walnuts and bananas.

Member States were invited to send their comments by 6 May 2024.

[24] Ethylene-bis-dithiocarbamates: maneb, mancozeb and metiram (+ nabam +further); Propylene-bis-dithiocarbamates: propineb (+further) and N,N-Dimethyldithiocarbamates: ziram and thiram (+ asomate, + ferbam +further)

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for fenbuconazole and penconazole in or on certain products

(PLAN/2024/23)

The Commission presented amendments made in version 1 and 2 of the draft Regulation addressing the confirmatory data submitted in response to the data gaps identified during the Article 12 MRL review for fenbuconazole and penconazole. Editorial changes had been made and the Regulation text now includes information where footnotes had been deleted.

The 45th session of the Codex Alimentarius Commission (CAC) adopted a CXL for fenbuconazole in tea. It is not implemented in the EU yet as another related legislative process was ongoing at the time in 2022. That MRL has now been included in this measure. The new proposed MRL for fenbuconazole in tea is 30 mg/kg replacing 0.05 mg/kg.

Fenbuconazole in mandarins: for the data gap on occurrence of triazole derivative metabolites (TDMs), the applicant suggested to extrapolate residue data. EFSA noted in their evaluation[25] that the data of trials submitted are not sufficient for extrapolation to the whole group of citrus fruits. The MRL is maintained at the current level which corresponds already to the CXL (0.5 mg/kg).

Penconazole in honey: the MRL is now proposed to be adjusted in line with the applicable Commission Working Document[26].

One Member State noted that the TRVs for fenbuconazole established by JMPR are lower than the EU ones. It should be noted that EFSA had not reviewed the TRVs during the confirmatory data assessment. The Commission suggested that the current work under this PLAN/2024/23 is first completed. Then, together with other non-approved substances in the same situation fenbuconazole TRVs could be assessed under the same mandate to EFSA.

Member States were invited to send their comments by 6 May 2024.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for isopyrazam in or on certain products

(PLAN/2023/2927)

The Commission presented the first version of a draft Regulation reviewing the MRLs for the non-approved substance isopyrazam under Article 12 of Regulation (EC) No 396/2005. The substance was part of the draft Regulation under agenda item B 05.00 (PLAN/2023/1960) in the past. As some Member States had indicated that they intended to vote against the draft Regulation if isopyrazam remains there, the Commission decided to draft a separate Regulation for isopyrazam. Nevertheless, several Member States already informed the Committee that they intend to vote against the measure as this substance meets the cut off criteria of Regulation (EC) No 1107/2009. As a next step, the Commission will notify trading partners under the WTO-SPS agreement.

[25] https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2023.8205

[26] Working Document on drafting proposal to amend pesticides MRLs following Art. 12 of Reg. (EC) No 396/2005 - Rev. 9 (11/05/2023)

Member States were invited to send comments by 6 May 2024.

C.05 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for thiacloprid in or on certain products

(PLAN/2023/961)

The Commission presented a new revision of a draft Regulation reviewing the MRLs for thiacloprid based on the indications that thiacloprid is a possible endocrine disruptor (ED), as identified by EFSA[27]. The Commission will mandate EFSA to conclude the assessment of the possible ED properties and the bee toxicity of thiacloprid. Pending the conclusion of this additional risk assessment and given the available pertinent information on potentially harmful effects on human health, the draft Regulation proposes to provisionally lower all thiacloprid MRLs to the product specific LOD. One Member State requested the revision of the proposed transitional measures, due to exceedances identified with some of the existing MRLs based on obsolete EU uses.

Member States were invited to send comments by 29 April 2024.

C.06 Exchange of views of the Committee on a draft Commission Regulation as regards methods of sampling and analysis for the control of pesticide residues in and on products of plant origin and repealing Directive 2002/63/EC

(PLAN/2023/636)

The Commission presented the first version of a new draft Sampling Regulation reflecting the work of the Sampling Working Group (see agenda item A. 09). Member States were asked to liaise with their sampling/laboratory experts when reviewing the text and Annex of the draft Sampling Regulation and suggest specific amendments. A Member State re-iterated its concerns raised in the Working group with the application of the measurement uncertainty and requested a possibility to apply a zero-measurement uncertainty in certain cases of health concerns. The Commission replied that the measurement uncertainty was an analytical necessity, and that zero uncertainty is analytically impossible.

Member States were invited to send comments by 13 May 2024.

C.07 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for zoxamide in or on certain products

(PLAN/2024/307)

Commission presented the first version of a draft Regulation reviewing MRLs for the active substance zoxamide under Article 12 of Regulation (EC) No 396/2005 and addressing an import tolerance request favourably assessed by EFSA. As a next step, the Commission will launch its internal consultation procedure of other Commission services and notify trading partners under the WTO-SPS agreement.

Member States were invited to send comments by 6 May 2024.

[27] EFSA conclusion peer review of the pesticide risk assessment of the active substance thiacloprid. EFSA Journal 2019;17(2):5595